

Year-at-A-Glance

Arizona LawHealth Law & Policy

Graduate/Undergraduate Course Offerings

Regulatory Science ▼ Health Law for Health Professionals ▼ Aging Law & Policy ▼ Health Information Privacy, Compliance, and Data Security

Arizona Law's Health Law and Policy Program is composed of over 40 online course offerings across four Certificate programs, spanning Regulatory Science, Health Law for Health Professionals, Aging Law & Policy and Health Information Privacy, Compliance, and Data Security.

Each Certificate requires a student to complete four courses for a total of 12 credit units. Students may substitute courses across Certificates to tailor a personalized program to meet personal and professional goals. All courses and Certificates may be applied towards the following degree programs: Master of Legal Studies in Health Law & Policy (MLS), Master of Laws (LLM), Juris Doctor (JD), or Bachelor of Arts in Law (BA) for students taking undergraduate health law courses.

LEARN MORE:

Contact us with any questions, to request further information, or to join our email listsery: law-healthcare@arizona.edu

Website: law.arizona.edu/health

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YouTube Health Law Channel



Graduate/Undergraduate Course Offerings Arizona Law Health Law & Policy **Year-at-A-Glance**

There is a large and increasing need for current and future pharmaceutical and medical device professionals, regulators, entrepreneurs, and scientists to have specialized training in translating research into new interventions for safe and effective medical products.

Spring 2

Summer 1

Summer 2

to Reach the Marketplace Fall 1 Graduate Level: Law 576A Co-instructors: John-Michael Sauer, PhD, and Huong Huynh, PhD, College of Law and Critical Path Institute **Regulatory Science Case Study Project** Graduate Level: Law 589A **Instructor:** Stephen Karpen, PharmD College of Law and Critical Path Institute Regulatory Science Colloquium (1 Unit) **Clinical Research Ethics** Spring 1 Graduate Level: Law 575A

Graduate Level: Law 695D (Also Available Spring 2)

Drug Discovery, Development & Innovation

Instructor: Kirin Goff, JD, MPH Colleges of Law and Public Health

Instructor: Mabel Crescioni, DrPH, JD, LLM, Colleges of Law & Public Health

Development & Innovation in Biologics, **Devices, & Diagnostics**

Graduate Level: Law 577A

Instructors: Marco Schito, PhD, College of Law and Critical Path Institute, and Christina Higgins, PhD, Critical Path Institute

Regulatory Science Colloquium (1 Unit)

Graduate Level: Law 695D (Also Available Fall 2)

Instructor: Kirin Goff, JD, MPH, Colleges of Law and Public Health

Translational Pathways for Medical Devices

Graduate Level: Law 588A, Undergraduate Level: Law 488A

Instructor: Nabil Dib, MD, College of Law, International Society for Cardiovascular Translational Research, and Dignity Health

Access to Investigational Medical Products: Clinical Trials, Expanded Access, & Right to Try Graduate Level: Law 590A, Undergraduate Level: Law 490A

Co-instructors: Alison Bateman-House, PhD, MPH,MA, College of Law and NYU Grossman School of Medicine, and Sage Gustafson, MA, College of Law and NYU Langone Health

Better understand and navigate the drug development process, including the full range of drug regulation from discovery, innovative drug development tools, and the postapproval phase. The course includes the Food and Drug Administration and international regulatory perspectives on bringing drugs through clinical trials to market in the US and abroad. (3 Units)

How can a didactic regulatory science education be translated and applied to real world challenges? In this course, students will integrate and apply their knowledge of regulatory science to the challenges faced every day by industry and regulatory decision makers. Leaders in the field will present case-based scenarios, and students will work in teams to discuss and problem-solve historic, current, and emerging topics in regulatory science. (3 Units)

This colloquium is offered twice a year and features leaders in the field presenting on cutting-edge issues in regulatory science. This course explores the role of executive agencies, such as the FDA, in ensuring safe and effective products to promote public health and address challenges for enforcement in a globalized world. (1 Unit)

This course explains the ethical principles underlying regulations and guidance governing clinical trials, especially as the principles pertain to informed consent, disclosure, and conflict of interest. The course also outlines the elements and design of clinical trials, including federal regulations for research with human subject participants, including vulnerable populations, and international research ethics. The course concludes with the evolving role of research ethics in big data. (3 Units)

What are the fundamental incentives for development in the biomedical space? The topics covered in this course include introducing key concepts in oversight by the FDA, biologics and biosimilars, regulation of diagnostics, along with the medical device development and approval process. The course concludes with a survey of Intellectual Property rights governing medical products, and the regulatory challenges in international markets. (3 Units)

This colloquium is offered twice a year and features leaders in the field presenting on cutting-edge issues in regulatory science. This course explores the role of executive agencies, such as the FDA, in ensuring safe and effective products to promote public health and address challenges for enforcement in a globalized world. (1 Unit)

This course focuses on the process of bringing medical devices from conceptualization to the bedside. There are a myriad of stakeholders and steps involved in this translational research process, which include: proof of concept, preclinical investigation, clinical application, regulatory assessment, reimbursement, and post-marketing evaluation. Ultimately, this course provides step-by-step explanations of the science, regulations, and reimbursement in medical device development, all with the aim to bring therapy to patients that improve survival and the quality of life. (3 Units) *Law 577A is highly recommended as a prerequisite.

Trace the historical evolution of policy and clinical practice for patients access to drugs prior to approval by the Food and Drug Administration. Students examine existing and emerging challenges, such as therapeutic misconception, crowd-funding, real world data collection, and preapproval access to gene therapies. (3 Units)

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zona Law Health Law & Policy **Graduate/Undergraduate** ear-at-A-Glance

Advance your career in health care by acquiring a fundamental understanding of the laws, regulations, and ethics surrounding the health care industry. This Certificate covers a range of topics including, business arrangements with insurers and providers, delivery of health care, and scope of practice.

Legal and Regulatory Aspects for Health Care Delivery Graduate Level: Law 578A, Undergraduate Level: Law 478A

Instructor: Tracy Nuckolls, JD, College of Law

Fall 1

7 Fall

Spring 3

Summer 1

Summer 2

Become familiar with the different models for how health care is organized and delivered through the licensure and accreditation process. The regulatory requirements for employment at health facilities through medical staff membership will also be covered. The course concludes with an in-depth focus on compliance requirements and privacy protection with advances in health technology, including health information exchanges. (3 Units)

Introduction to Biomedical Informatics

Graduate Level: Law 577, Undergraduate Level: Law 477

Instructor: Vignesh Subbian, PhD. Colleges of Law and Engineering

This course surveys the field of biomedical informatics, including the effective uses of biomedical data collected from individuals (patients) and populations for scientific inquiry, problem solving, and decision making. In addition, ethical, legal, and social implications of medical informatics are covered, with emphasis on technology ethics, digital health regulations, and privacy laws. (3 Units)

Legal & Regulatory Fundamentals of Health Care Business

Graduate Level: Law 579B, Undergraduate Level: 479B

Instructor: Christopher Mathis, JD, MPA, MPH, College of Law

Acquire a fundamental understanding of the financial management and regulatory issues in the health law field, specifically related to reimbursement, Medicare and Medicaid, and federal laws governing fraud and abuse. Course also covers long- term care, in terms of planning, financing, and placement. (3 Units)

Health Care Ethics

Graduate Level: Law 515

Instructor: Laura Howard, PhD, College of Law

Explore moral and ethical questions faced by health professionals in the delivery of health care services. What rights and responsibilities come with the role of a health care provider? Should a provider always disclose the full truth about a diagnosis? (3 Units)

Public Health Law & Ethics

Graduate Level: Law 608A

Instructor: Leila Barraza, JD, MPH. Colleges of Law and Public Health

This course examines the constitutional underpinnings of public health interventions. In addition, students will learn about the respective roles of local, state, tribal, and federal governments with respect to public health, and reflect on the balance between individual rights and governmental interests in protecting the public's health. (3 Units)

Liability & Regulation of Health Care Professionals

Graduate Level: Law 580A, Undergraduate Level: Law 480A

Instructor: Elizabeth Hall-Lipsy, JD, MPH, Colleges of Law and Pharmacy

Gain an overview of the scope of practice licensing and compliance requirements that govern health professionals, along with training in the role of expert witnesses in litigation from the deposition process to trial. Administrative, criminal and civil processes for non-compliance will also be covered. (3 Units)

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Course Offering



for professionals

Fall 1

Fall 2

Spring 1

Spring 2

Graduate/Undergraduate Course Offerings Arizona Law Health Law & Policv **Year-at-A-Glance**

who work in the aging sector to better understand the legal and ethical issues that surround working later-in-life, long-term care, and the role of technology changing how health care is monitored and delivered to older adults.

Technology and Aging: Legal & Ethical Developments

Graduate Level: Law 584C, Undergraduate Level: Law 484C

Instructor: Kathryn Huber, PhD, College of Law and University of Colorado School of Medicine

This course provides an in-depth look at the ethical, legal, and social challenges facing aging adults amidst the rise of novel technologies. Long-term care is at the frontier of data-driven technologies, which are regularly touted as a way forward to address many issues unique to older adults, including frailty, falls, and loss of functional independence. This course discusses the promises new technologies could offer an aging workforce and their pitfalls. (3 Units)

Aging and the Law

Graduate Level: Law 584D, Undergraduate Level: Law 484D

Available Fall 2022

Legal, ethical, and social issues arise in relation to caring for an older population. Special attention in this course is given to: elder abuse, neglect, and financial exploitation; healthcare decision making. including advance directives and end-of-life issues; ethical issues in elder representation; and other family issues, including "grandparents as parents," and later-in-life marriages. (3 Units)

Aging in America

Graduate Level: 584A, Undergraduate Level: 484A

Instructor: Christopher Mathis, JD, MPA, MPH, College of Law

This course provides a fundamental understanding of legal and public health frameworks involved in the financing and delivery of care for the US aging population. Course covers funding models from Medicare and Medicaid to Veterans Administration and Indian Health Service. In addition, long-term care and care-giving challenges are a focus and emerging trends, such as working later-in-life, loneliness and isolation, opioid addiction, and emergency preparedness. (3 Units)

Aging and Social Justice

Graduate Level: Law 584B, Undergraduate Level: Law 484B

Instructor: Laura Howard, PhD, College of Law

This course covers the terrain of age discrimination, social conceptions of older adults as burdensome and cultural biases that reject the role of the elderly as valuable contributors. (3 Units)



Offerings Arizona Law Health Law & Policy Course **Graduate/Undergraduate Year-at-A-Glance**

In this digital age, it is essential for health professionals to be able to

Health Information Technology

Graduate Level: Law 580C, Undergraduate Level: Law 480C

Instructor: Chase Millea, JD, College of Law and Snell & Wilmer L.L.P.

The world of health information technology is rapidly changing with the adoption of electronic health records and the advancement of health information technology. The right information in the right hands at the right time is critical to effective patient care. This course provides an overview of the laws and regulations governing the use and disclosure of patient health information with a focus on patient rights in age of big data, data-sharing, and information blocking. (3 Units)

Introduction to Biomedical Informatics

Graduate Level: Law 577, Undergraduate Level: Law 477

Instructor: Vignesh Subbian, PhD, Colleges of Law and Engineering

This course surveys the field of biomedical informatics, including the effective uses of biomedical data collected from individuals (patients) and populations for scientific inquiry, problem solving, and decision making. In addition, ethical, legal, and social implications of medical informatics are covered, with emphasis on technology ethics, digital health regulations, and privacy laws. (3 Units)

Introduction to Privacy

Graduate Level: Law 580, Undergraduate Level: Law 480

Instructor: Jane Bambauer, JD, College of Law

This course explores a range of contexts in which the courts and other branches of government have attempted to give definition to a legal right to privacy. The right to privacy is puzzling and evolving area with technology advancements. Courts and policymakers grapple with the rules that ought to govern the collection and use of personal information. (3 Units)

Data Privacy & Cybersecurity in Health Care

Graduate Level: Law 580B, Undergraduate Level: 480B

Instructor: John Howard, JD, College of Law and UA Office for Research, Innovation, and Impact

Better understand health data privacy and cybersecurity in the context of how companies structure, negotiate, and protect their commercial and compliance relationships. Specific topics include clinical research and privacy; risk management; health data security; and data security breaches. (3 Units)

Spring 2

Fall 1

Fall 2

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